



Mailed March 4, 2002

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MAR 04 2002 In Re: Patent Term Extension

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Application for
U.S. Patent No. 5,236,952

REEXAM UNIT

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,236,952, which claims the human drug TASMAR® (tolcapone), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 530 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 530 days.

The period of extension has been calculated using the Food and Drug Administration (FDA) determination of the length of the regulatory review period published in the Federal Register of November 27, 1998 (63 Fed. Reg. 65599). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,014 - 990) + 604 \\ &= 1,116 \text{ days}\end{aligned}$$

Since the regulatory review period began December 1, 1990, before the patent issued (August 17, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 1, 1990 to August 17, 1993 is 990 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (January 29, 1998) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above 1,116 days, would extend the patent to September 6, 2013, which is beyond the 14 year limit (14 years after the approval date is January 29, 1998) set forth in 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its expiration date, August 17, 2010, to and including January 29, 2012, or 530 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

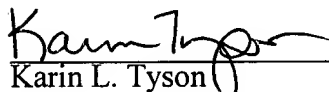
U.S. Patent No.	:	5,236,952
Granted	:	August 17, 1993
Original Expiration Date	:	August 17, 2010
Applicant	:	Karl Bernauer, et al.
Owner of Record	:	Hoffmann- La Roche Inc.
Title	:	CATECHOL DERIVATIVES
Classification	:	514/520
Product Trade Name	:	TASMAR® (tolcapone)
Term Extended	:	530 days
Expiration Date of Extension	:	January 29, 2012

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
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RE: TASMAR® (tolcapone)
FDA Docket No.: 95E-0480